

# PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:  
**BIANCHETTI BRACCO MINOJA S.R.L.**  
 Attn. Banfi, Paolo  
 Via Rossini, 8  
 I-20122 Milano  
 ITALY

**RICEVUTO  
RECEIVED ON**

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**BIANCHETTI-BRACCO-MINOJA srl**

# PCT

## INVITATION TO PAY ADDITIONAL FEES

(PCT Article 17(3)(a) and Rule 40.1)

## REGISTERED

Applicant's or agent's file reference  
**SCB 844 PCT**

International application No.  
**PCT/EP2004/002185**

Applicant

**ISTITUTO NAZIONALE PER LO STUDIO E LA CURA DEI ...**

Date of mailing  
 (day/month/year)

19/07/2004

**PAYMENT DUE**

within 30 ~~max~~ days from the above date of mailing

International filing date  
 (day/month/year)

04/03/2004

1. This International Searching Authority

(i) considers that there are 2 (number of) inventions claimed in the international application covered by the claims indicated ~~XXXXX~~ on the extra sheet:

and it considers that the international application does not comply with the requirements of unity of invention (Rules 13.1, 13.2 and 13.3) for the reasons indicated ~~XXXXX~~ on the extra sheet:

(ii)  has carried out a partial international search (see Annex)  will establish the international search report on those parts of the international application which relate to the invention first mentioned in claims Nos.:  
 see annex

(iii) will establish the international search report on the other parts of the international application only if, and to the extent to which, additional fees are paid

2. The applicant is hereby invited, within the time limit indicated above, to pay the amount indicated below:

EUR 1.550,00 x 1 = EUR 0,00  
 Fee per additional invention      number of additional inventions      total amount of additional fees

Or,                          x                          =                         

The applicant is informed that, according to Rule 40.2(c), the payment of any additional fee may be made under protest, i.e., a reasoned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional fee is excessive.

3.  Claim(s) Nos.                          have been found to be unsearchable under Article 17(2)(b) because of defects under Article 17(2)(a) and therefore have not been included with any invention.

Name and mailing address of the International Searching Authority  
 European Patent Office, P.B. 5818 Patentlaan 2  
 NL-2280 HV Rijswijk  
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
 Fax: (+31-70) 340-3016

Authorized officer

**Joannes Vergoosen**

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-17, 19, 20

ALK assay using a peptide of SEQ ID N. 1 or SEQ ID N. 2 and said peptides and related kits.

2. claim: 18

Use of compounds of formula (I) for the preparation of a medicament for the treatment of ALK-related tumors.

The present application lacks unity of invention in the sense of Rule 13.1 and 13.2 PCT.

The application as filed is considered to lack unity of invention since its subject-matter relates not to one, but rather to two separate inventions not linked together by a common underlying inventive concept as required by Rule 13.1 and 13.2 PCT.

The claims and the inventions to which the two separate inventions relate may be grouped together as follows:

Invention 1: Claims 1-17, 19, 20  
Invention 2: Claim 18

According to Rule 13.2 PCT, an international patent application must relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding special technical features. Special technical features are such features that define the contribution of the claimed invention over the prior art.

The contributions claimed in the present application which are allegedly made over the prior art are:

- a) the use of a peptide according to SEQ ID N. 1 or 2 as a substrate for ALK,
- b) the use of a compound according to formula (I) to produce a medicament against an ALK-related tumour.

These contributions are not so linked to form a single general inventive concept in the sense of Rule 13.1 and 13.2 PCT. The reasons therefor are the following:

The two identified inventions involve the common concept: "(identifying) modulators of ALK activity", as the sole common link. However, this concept does not define a contribution over the prior art, because it is not new (see for example US-A-5 770 421, column 14, lines 51-58). Thus, the common concept linking the alleged inventions is not new. Therefore, there is no single general inventive concept that links the claimed inventions, which results in non-unity of invention in the sense of Rule 13.1 and 13.2 PCT.

Annex to Form PCT/ISA/206  
COMMUNICATION RELATING TO THE RESULTS  
OF THE PARTIAL INTERNATIONAL SEARCH

International Application No  
**PCT/EP2004/002185**

1. The present communication is an Annex to the invitation to pay additional fees (Form PCT/ISA/206). It shows the results of the international search established on the parts of the international application which relate to the invention first mentioned in claims Nos.:
 

see 'Invitation to pay additional fees'
2. This communication is not the international search report which will be established according to Article 18 and Rule 13.
3. If the applicant does not pay any additional search fees, the information appearing in this communication will be considered as the result of the international search and will be included as such in the international search report.
4. If the applicant pays additional fees, the international search report will contain both the information appearing in this communication and the results of the international search on other parts of the international application for which such fees will have been paid.

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim N°
A	DATABASE WPI Section Ch, Week 199325 Derwent Publications Ltd., London, GB; Class A96, AN 1993-201126 XP002249142 & JP 05 126833 A (TOSOH CORP) 21 May 1993 (1993-05-21) abstract -----	1-17, 19, 20
A	US 5 770 421 A (LOOK A THOMAS ET AL) 23 June 1998 (1998-06-23) the whole document -----	1-17, 19, 20
A	WO 95/14930 A (SADICK MICHAEL DANIEL ;GENENTECH INC (US); GODOWSKI PAUL J (US); M) 1 June 1995 (1995-06-01) the whole document -----	1-17, 19, 20
A	WO 98/49317 A (PELES ELIOR ;ONRUST SUSAN (NZ); CLARY DOUGLAS (US); HUI TERANCE H) 5 November 1998 (1998-11-05) the whole document -----	1-17, 19, 20
A	WO 95/02187 A (BARKER KAREN TRACEY ;CROMPTON MARK ROGER (GB); MARTINDALE JANE ELI) 19 January 1995 (1995-01-19) the whole document -----	1-17, 19, 20
	-/-	

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

\* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*Z\* document member of the same patent family

Annex to Form PCT/ISA/206  
COMMUNICATION RELATING TO THE RESULTS  
OF THE PARTIAL INTERNATIONAL SEARCH

International Application No  
PCT/EP2004/002185

**C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT**

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	SADICK M D ET AL: "Kinase receptor activation (KIRA): A rapid and accurate alternative to end-point bioassays" JOURNAL OF PHARMACEUTICAL AND BIOMEDICAL ANALYSIS 1999 NETHERLANDS, vol. 19, no. 6, 1999, pages 883-891, XP002249139 ISSN: 0731-7085 the whole document	1-17, 19, 20
A	TURTURRO FRANCESCO ET AL: "Model of inhibition of the NPM-ALK kinase activity by herbimycin A." CLINICAL CANCER RESEARCH: AN OFFICIAL JOURNAL OF THE AMERICAN ASSOCIATION FOR CANCER RESEARCH. UNITED STATES JAN 2002, vol. 8, no. 1, January 2002 (2002-01), pages 240-245, XP002249140 ISSN: 1078-0432 the whole document	1-17, 19, 20
A	MORRIS STEPHAN W ET AL: "ALK, the chromosome 2 gene locus altered by the t(2;5) in non-Hodgkin's lymphoma, encodes a novel neural receptor tyrosine kinase that is highly related to leukocyte tyrosine kinase (LTK)." ONCOGENE, vol. 14, no. 18, 1997, pages 2175-2188, XP002249141 ISSN: 0950-9232 the whole document	1-17, 19, 20

**Patent Family Annex**

Information on patent family members

International Application No

**PCT/EP2004/002185**

Patent document cited in search report	Publication date	Patent-family member(s)		Publication date
JP 5126833	A 21-05-1993	NONE		
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**Patent Family Annex**

Information on patent family members

International Application No

**PCT/EP2004/002185**

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO 9849317	A	US 6388063	B1	14-05-2002
		US 2004087783	A1	06-05-2004

  

WO 9502187	A	19-01-1995	AU 7081094	A	06-02-1995
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			ZA 9404983	A	08-01-1996